

REMARKS

Applicants amend claims 13, 22, 39, and 71, cancel claim 21 without prejudice, and add new claims 73 and 74. All grounds of rejection are discussed in detail below. Application is believed to be in condition for allowance. Reconsideration and allowance are respectfully requested.

Rejections Under 35 USC 102

The Office Action rejects claims 13, 17, 18, 39, 40, 57-60 and 71 as being anticipated by U.S. Patent No. 5,814,008 of Chen.

Claim 1, as amended, recites an apparatus for performing a medical procedure on a treatment area of a patient's body that contains at least one chromophore. The apparatus includes a source of electromagnetic radiation (EMR) of at least one wavelength absorbed by the chromophore, an applicator for applying the EMR to the treatment area of a patient's body, which includes a target area thermally coupled to the chromophore. The apparatus further includes controls causing the EMR applied to the chromophore to have a power profile with an average power (P_a) for heating the chromophore and a peak power (P_p) that is insufficient to cause a change in the chromophore which would result in a significant loss of absorption. The power profile has a duration significantly greater than a thermal relaxation time (TRT) for the target area and is adapted to allow raising a temperature of the target area via thermal coupling to the heated chromophore to an elevated value that can cause *cellular* thermal damage in at least a portion of the target area.

Chen is directed to methods and apparatus for performing photodynamic therapy (PDT). Chen discloses a PDT probe that can be disposed in a patient's body in proximity of tumor tissue to be treated. The probe can include a light source generating radiation that can be absorbed by a drug administered to the tissue to initiate photodynamic therapy. It can further include a heat source, e.g., another light source, that can heat the

tumor tissue prior, during, and/or after therapy to enhance the efficacy of the treatment, for example, by increasing perfusion of the administered drug through the tissue.

Chen does not teach controls that would cause the heat source to heat a chromophore so as to raise the temperature of a target area, which is thermally coupled to the chromophore, to a sufficiently elevated value that would cause *thermal damage* in at least a portion of the target area. Rather, the heat source in Chen is simply employed for increasing perfusion of an administered drug to a diseased tissue, and not to cause thermal damage in that tissue.

Hence, claim 13, and claims 17, 18 that depend on claim 13, distinguish patentably over Chen.

In view of the Examiner's general remarks in the Office Action regarding the lack of specific ranges in the claims for certain parameters, claim 39 is amended to recite that the source of electromagnetic radiation generates wavelengths in a range of about 400 to about 1500 nm. More specifically, claim 39, as amended, recites an apparatus for performing a medical procedure on a target area of a patient's body, which exhibits a thermal relaxation time (TRT) and includes a highly absorbent heater portion. The apparatus includes an EMR source that *generates radiation with wavelengths in a range of about 400 to about 1500 nm* and an applicator for applying radiation from the source to the heater portion. The apparatus further includes controls for operating the source and/or the applicator to apply radiation to the target area for a duration significantly greater than the thermal relaxation time and with a power profile that is adapted to cause heating of the heater portion to an elevated temperature that is sufficient to heat the remainder of the target area via heat diffusion from the heater portion to a temperature that can *cause a structural change* in at least portion of the target area while ensuring that the heater temperature is insufficient for causing a substantial change in the absorption of the radiation by the heater portion.

In Chen, the heating of the tumor simply enhances blood perfusion (and consequently perfusion of a PDT drug administered to the circulatory system) through a

tumor, and is not intended to cause any structural change (e.g., denaturing of a protein) of the tumor. In contrast, claim 39 recites controls for operating the light source and/or the applicator in such a way as to heat the target area, via thermal coupling to a radiation-absorbing heater, to cause a *structural change* in at least a portion of the target area – features not taught by Chen. Hence, claim 39 and 40, which depends on claim 39, distinguish patentably over Chen.

Further, claim 57 recites an apparatus for performing a medical procedure on a target area of a patient's body, which includes a highly absorbent heater portion. The apparatus includes a source of electromagnetic radiation (EMR) generating radiation having at least one wavelength that can be highly absorbed by the heater portion and an applicator for applying the radiation to the heater portion of the target area. The apparatus further includes controls for controlling at least one of the source and the applicator to cause the EMR applied to that target area to have adjustable flux and power profile for heating the heater portion to a temperature T that is *greater than a temperature for causing cellular thermal damage in at least a portion of the target*. The temperature T is, however, less than a collapse temperature at which the heater portion undergoes a change that would result in a significant loss in its absorption of radiation. Moreover, the power profile has a temporal duration that is sufficient for accomplishing the medical dermatology procedure.

The arguments presented above with respect to claim 13 apply with equal force to establish that claim 57 is also patentable over Chen. In particular, Chen does not teach controls that would control a radiation source irradiating a heater portion of a target area so as to heat the heater portion to a temperature that is *greater than a temperature for causing cellular thermal damage in at least a portion of the target*. Hence, claim 57, and claims 58-60 that depend on claim 57, distinguish patentably over Chen.

Independent apparatus claim 71 is amended to recite that the EMR source generates at least one wavelength that lies either in a range of about 0.95 microns to about 1.9 microns or in a range of about 2.1 microns to about 2.4 microns. Although

Chen discloses employing light sources (e.g., LED's) for heating the tumor, it does not teach these wavelength ranges. In addition, claim 71 is amended to recite the radiation power profile is sufficient to cause a structural change in at least a portion of the target area – another feature not taught by Chen as discussed in detail above. Thus, similar to claim 39, claim 71 is also patentable over Chen.

The Office Action rejects claims 37-44, 57, 58, 60, 66, 68, and 71 as being anticipated by U.S. Patent No. 5,660,836 of Knowlton.

As an initial matter, Applicants note that claims 37 and 38 are withdrawn, and hence will not be discussed any further here. The remaining claims distinguish over this patent of Knowlton for the following reasons.

The '836 patent is directed to an apparatus for applying radiant energy through a subject's skin to underlying collagen tissue. The apparatus includes a porous membrane having an external surface that can be placed in thermal contact with a subject's epidermis. The membrane includes a cooling lumen for receiving a cooling fluid that can cool the epidermis layer while a plurality of radio frequency (RF) electrodes positioned in the membrane apply radiation energy – via an electrolyte solution introduced into the porous membrane that passes by the electrodes – through the epidermis to the underlying collagen. In this manner, a reverse thermal gradient is generated from the epidermis to the underlying collagen tissue that can cause the hydrolysis of heat labile cross links of the collagen tissue. In some embodiments, the apparatus can include a focusing element for focusing thermal energy from the electrolytic solution to the underlying collagen tissue.

Unlike amended claim 39, the '836 patent of Knowlton does not teach a radiation source that generates radiation in a range of about 400 nm to about 1500 nm. Rather, Knowlton utilizes radiofrequency (RF) radiation for heating the electrolytic solution. Thus, claim 39, and claims 40-44 that depend either directly or indirectly on claim 39, distinguish over the teachings of the '836 patent.

Claim 57 distinguishes over the '836 patent at least because it recites controls to cause the source to generate a power profile that heats the heater to a temperature that is greater than a temperature for causing *cellular* thermal damage in at least a portion of the target to be damaged – a feature not taught by the '836 patent. In particular, Knowlton does not teach causing damage to *cells* via heating, but simply describes heating an underlying collagen (a structural protein) for partially denaturing it.

Claims 58 and 60 depend on claim 57, and distinguish over the '836 patent of Knowlton, as well.

With regard to claim 66, Applicants note that the apparatus recited in this claim includes a source of electromagnetic radiation that generates a wavelength that is absorbed by melanin in the patient's epidermis. Knowlton does not teach such a radiation source. In fact, the RF radiation generated by the electrodes of Knowlton is intended to be absorbed by an electrolytic solution, and not melanin. Hence, claim 66, as well as claims 67 and 68 that depend on claim 66, distinguish over this patent of Knowlton.

Further, independent claim 71 recites that the radiation source generates radiation with wavelength components in a range of about 0.95 microns to about 2.1 microns, or in a range of about 2.1 microns to about 2.4 microns. In contrast, the '836 patent teaches RF sources, and not sources generating radiation in the infrared portion of the electromagnetic spectrum.

The Office Action rejects claims 13, 16-27, 39-44, 43, 57-60, 66-68, 71 and 72 as being anticipated by U.S. Patent No. 6,350,276 of Knowlton.

The '276 patent is directed to an apparatus for applying electromagnetic energy and mechanical force to a skin tissue, e.g., collagen containing tissue, to provide remodeling of the collagen. The apparatus includes a template that receives a selected skin portion, and includes a surface for applying pressure to that skin portion. An energy generating device, e.g., an RF source, can be coupled to the template for applying energy

to the skin portion and/or the underlying tissue. A fluid delivery device delivers a cooling fluid to the tissue interface to remove heat from the skin and the underlying tissue. The fluid delivery device may also deliver cooling fluid to the template and/or the energy generating device to dissipate heat therefrom. In some embodiments, a reverse thermal gradient is established between the skin surface and the underlying tissue to avoid thermal damage to the skin.

Unlike claim 13, the '276 patent does not teach controls that would cause the radiation source to effect heating of a target area, via heating a chromophore thermally coupled to that area, to an elevated temperature that would cause *cellular* thermal damage in at least a portion of the target area. The '276 patent discloses remodeling of collagen, and not causing thermal damage to cells. Further, claims 16-27 depend, either directly or indirectly on claim 13, and hence incorporate at least the patentable features of this claim.

Further, the '276 patent does not teach the wavelength range of about 400 nm to about 1500 nm recited in claim 39, but rather discloses an RF energy source for heating the skin. Moreover, although in col. 7, lines 51-66, Knowlton states that the energy source can be a coherent or an incoherent light source, it does not teach, or even suggest, a light source generating radiation with wavelengths in a range of about 400 to about 1500 nm, recited in claim 39. Thus, claim 39, and claims 40-44 that depend either directly or indirectly on claim 39, are patentable over the '276 patent.

With regard to independent claim 57, the '276 patent does not teach controls that operate a heating EMR source so as to generate a power profile that would cause the temperature of a heater portion within a target area to rise above a temperature for causing *cellular* thermal damage. In contrast, the '276 patent teaches remodeling of collagen, and not causing thermal damage to cells. Thus, claims 57, and 58-60 dependent thereon, distinguish over the teachings of the '276 patent.

With regard to claim 66, the '276 patent does not teach a radiation source for generating wavelengths that are absorbed by melanin. Rather, the RF source in

Knowlton is utilized to heat a heat-transfer fluid, such as a saline solution, alcohol, and the like.

With regard to claim 71, the '276 patent does not teach a radiation source that would generate wavelengths that can be either in a range of about 0.95 microns to about 1.9 microns, or in a range of about 2.1 microns to about 2.4 microns, recited in claim 71. Thus, claim 71, and claim 72 that depends on claim 71, distinguish over the teachings of the '276 patent.

New Claims

New claim 73 depends on claim 39 and further recites that the apparatus is useful for wrinkle removal and that the heater portion comprises melanin in the DE junction. In addition, claim 73 recites that the target area comprises collagen in the papillary dermis and that the heating of the target area causes restructuring of the collagen. New claim 74 depends on claim 71, and further recites that the apparatus is useful for wrinkle removal and that the heater portion comprises water. In addition, claim 74 recites that the target area comprises collagen in thermal coupling with the water and that the power profile causes restructuring of the collagen.

Support for the new claims can be found in original claims (e.g., original claim 21, canceled in this response) and throughout the remainder of the specification. Thus, no new matter is added. As discussed in detail above, independent amended claims 39 and 71 distinguish patentably over the cited art, and hence so do claims 73 and 74 that depend on claim 39 and 71, respectively.

Application No. 09/769,960
Reply to Office action of March 24, 2004

Group Art Unit: 3739
Examiner: David M. Shay
Atty. Docket No. 105159-29

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully request reconsideration and allowance of the application. Applicants invite the Examiner to call the undersigned at (617) 439-2514 if there are any remaining questions.

Respectfully submitted,

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Date: September 24, 2004

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